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NEWS DETAILS

Masimo Announces FDA Clearance of Pediatric Indication for SedLine® Brain Function Monitoring and the SedLine Pediatric EEG Sensor

02/28/2022

SedLine's Advanced Depth of Anesthesia Monitoring Now Cleared for Use on Patients as Young as 1 Year Old in the United States

IRVINE, Calif.--(BUSINESS WIRE)-- Masimo (NASDAQ: MASI) announced today the FDA clearance of SedLine® brain function monitoring for pediatric patients (1-17 years of age) and the SedLine Pediatric EEG Sensor. With this clearance, the potential benefits of SedLine have been expanded to all patients one year old and above in the United States. Equipped with Masimo's advanced signal processing technology, SedLine helps clinicians monitor brain activity bilaterally by processing electroencephalogram (EEG) signals from Masimo's four-lead SedLine EEG sensors.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20220228005286/en/>



Masimo SedLine® Brain Function Monitoring (Photo: Business Wire)

This clearance brings Masimo's bilateral brain activity monitoring to children 1 to 17 years old, in conjunction with specially sized pediatric sensors designed for easier application on smaller pediatric foreheads. Brain activity monitoring under anesthesia on pediatric patients is different from that of adults.¹⁻² Maintaining an appropriate depth of anesthesia is key to preventing anesthesia-related events and enabling faster recovery.³ To aid clinicians in monitoring anesthesia depth on children, SedLine features both the display of EEG signals and the Multitaper Density Spectral Array (DSA) from both sides of the brain, to provide clinicians with a more complete picture of the brain.

Dr. Cristina Verdú of Hospital Universitario La Paz, Madrid, Spain, said, "SedLine is an easy window into a child's electroencephalogram. It helps us to personalize sedoanalgesia. Now, we can choose the appropriate dose according to its effects, not just according to weight or age. But in addition to monitoring anesthetic depth, it allows us to detect warning signs such as asymmetries or seizures; it tells us what is happening to the child's brain."

Joe Kiani, Founder and CEO of Masimo, said, "SedLine is achieving for brain function monitoring what Masimo SET® did for pulse oximetry. We believe SedLine is the best and most advanced way to monitor depth of sedation, crucial to helping ensure patients with even the most challenging and the youngest brains are appropriately anesthetized. We are proud to be able to bring its benefits to children in the United States."

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About Masimo

Masimo (NASDAQ: MASI) is a global medical technology company that develops and produces a wide array of industry-leading monitoring technologies, including innovative measurements, sensors, patient monitors, and automation and connectivity solutions. Our mission is to improve patient outcomes and reduce the cost of care. Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry, introduced in 1995, has been shown in over 100 independent and objective studies to outperform other pulse oximetry technologies.⁴ Masimo SET® has also been shown to help clinicians reduce severe retinopathy of prematurity in neonates,⁵ improve CCHD screening in newborns,⁶ and, when used for continuous monitoring with Masimo Patient SafetyNet™ in post-surgical wards, reduce rapid response team activations, ICU transfers, and costs.⁷⁻¹⁰ Masimo SET® is estimated to be used on more than 200 million patients in leading hospitals and other healthcare settings around the world,¹¹ and is the primary pulse oximetry at 9 of the top 10 hospitals as ranked in the 2021-22 U.S. News and World Report Best Hospitals Honor Roll.¹² Masimo continues to refine SET® and in 2018, announced that SpO₂ accuracy on RD SET® sensors during conditions of motion has been significantly improved, providing clinicians with even greater confidence that the SpO₂ values they rely on accurately reflect a patient's physiological status. In 2005, Masimo introduced rainbow® Pulse CO-Oximetry technology, allowing noninvasive and continuous monitoring of blood constituents that previously could only be measured invasively, including total hemoglobin (SpHb™), oxygen content (SpOC™), carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), Pleth Variability Index (PVI®), RPVI™ (rainbow® PVI), and Oxygen Reserve Index (ORi™). In 2013, Masimo introduced the Root® Patient Monitoring and Connectivity Platform, built from the ground up to be as flexible and expandable as possible to facilitate the addition of other Masimo and third-party monitoring technologies; key Masimo additions include Next Generation SedLine® Brain Function Monitoring, O3® Regional Oximetry, and ISA™ Capnography with NomoLine® sampling lines. Masimo's family of continuous and spot-check monitoring Pulse CO-Oximeters includes devices designed for use in a variety of clinical and non-clinical scenarios, including tetherless, wearable technology, such as Radius-7® and Radius PPG™, portable devices like Rad-67®, fingertip pulse oximeters like MightySat® Rx, and devices available for use both in the hospital and at home, such as Rad-97®. Masimo hospital automation and connectivity solutions are centered around the Masimo Hospital Automation™ platform, and include Iris® Gateway, iSirona™, Patient SafetyNet®, Replica®, Halo ION™, UniView®, UniView :60™, and Masimo SafetyNet®. Additional information about Masimo and its products may be found at www.masimo.com. Published clinical studies on Masimo products can be found at www.masimo.com/evidence/featured-studies/feature/.



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4. Published clinical studies on pulse oximetry and the benefits of Masimo SET[®] can be found on our website at <http://www.masimo.com>. Comparative studies include independent and objective studies which are comprised of abstracts presented at scientific meetings and peer-reviewed journal articles.
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Forward-Looking Statements

This press release includes forward-looking statements as defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, in connection with the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, among others, statements regarding the potential effectiveness of Masimo SedLine[®] and the SedLine Pediatric EEG Sensor, as well as their FDA clearance for pediatric patients. These forward-looking statements are based on current expectations about future events affecting us and are subject to risks and uncertainties, all of which are difficult to predict and many of which are beyond our control and could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements as a result of various risk factors, including, but not limited to: risks related to our assumptions regarding the repeatability of clinical results; risks related to our belief that Masimo's unique noninvasive measurement technologies, including SedLine, contribute to positive clinical outcomes and patient safety; risks that the researchers' conclusions and findings may be inaccurate; risks related to our belief that Masimo noninvasive medical breakthroughs provide cost-effective solutions and unique advantages; risks related to COVID-19; as well as other factors discussed in the "Risk Factors" section of our most recent reports filed with the Securities and Exchange Commission ("SEC"), which may be obtained for free at the SEC's website at www.sec.gov. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. We do not undertake any obligation to update, amend or clarify these statements or the "Risk Factors" contained in our most recent reports filed with the SEC, whether as a result of new information, future events or otherwise, except as may be required under the applicable securities laws.

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Masimo
Evan Lamb
949-396-3376
elamb@masimo.com

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Masimo SedLine[®] Brain Function Monitoring
(Photo: Business Wire)

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